



član skupine Sandoz
a Sandoz company

BATCH RELEASE CERTIFICATE

Product name: AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION

Code no.: 5200112

Batch no.: CK4884

Production date: 04.2012

Expiry date: 04.2015

Certificate of analysis: See attachment

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the MA of importing country. The batch processing, packaging and analysis records were reviewed and found in compliance with GMP.

Release date:
07.05.2012

The batch was released by:
GABRIJELA SVANJAK
(This document was electronically signed.)

Pharmaceutics d.d.
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Lek Pharmaceuticals d.d.
Penicillin Production Plant

Perzonal 47
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Phone: + 386 2/824 63 31
Fax: + 386 2/823 16 66

Quality Unit

Perzonal 47
2391 Prevalje, Slovenija
Phone: + 386 2/824 63 43
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CERTIFICATE OF ANALYSIS

Product 5200112 AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION
Number of MA F-14358/09
Lot No. CK4884

Parameters	Specifications	Results
Colour of content	white to yellowish white	conforms
Appearance of content	crystalline powder	conforms
Colour and appearance of suspension	almost white to yellow, homogeneous	conforms
Water	$\leq 8.5\%$	5.3 %
pH	4.2 - 6.5	5.1
Filling	NLT 17.5 g	conforms
Identification	amoxicillin	conforms
Identification	clavulanate potassium	conforms
Assay	360.0 - 480.0 mg/5ml amoxicillin: 400.0 mg/5ml	409.7 mg/5ml
Assay	51.30 - 71.25 mg/5ml clavulanic acid: 67.00 mg/5ml (90.0 - 125.0%)	62.26 mg/5ml
Total aerobic microbial count	NMT 10exp.3/g	*
Total yeasts and moulds count	NMT 10exp.2/g	*

* Not routinely tested. Test is performed according to approved testing frequency.
Electronically signed



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CERTIFICATE OF ANALYSIS

Product 5200112 AMBILAN BID 400/57 POWDER FOR ORAL SUSPENSION
Number of MA F-14358/09
Lot No. CK4884

Parameters	Specifications	Results
Escherichia coli	absent/g	✓
Storage	At a temperature below 30°C, in a dry place	
Complies with specification of Marketing Authorisation		
Date	07.05.2012	Quality Unit Dunja Frece-Oderlap



Lek Pharmaceuticals d.d.
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